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Robert J. Marshall

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PAULEY PETERSEN & ERICKSON  
2800 WEST HIGGINS ROAD  
SUITE 365  
HOFFMAN ESTATES, IL 60195

EXAMINER

UNDERDAHL, THANE E

ART UNIT

PAPER NUMBER

1651

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Please find below and/or attached an Office communication concerning this application or proceeding.



**Election/Restrictions**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group	Claims	Drawn to
I	1-3	A stabilized dihydrolipoic acid compound
II	4-12	A culture media comprising a probiotic, R-lipoic acid and a least one nutritive agent
III	13-15	Method to make dihydrolipoic acid in a culture media
IV	16-19	A method of making a beneficial compound

The inventions are distinct, each from the other because of the following reasons:

**DISTINCT PRODUCTS**

Inventions I and II are related as distinct products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the culture media listed in Group II can be used to produce strains of intestinal microorganisms (probiotics) that do not produce dihydrolipoic acid .

**PRODUCT AND MAKING**

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §

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806.05(f)). In the instant case the process steps in claim 13-14 can be used to produce other molecules than dihydrolipoic acid, such as the production and collection of secretory proteins.

#### DISTINCT PROCESSES

Inventions III and IV are distinct. Inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art) (MPEP § 802.01).

The processes are distinct from one another because they recite different and distinct steps, which lead to different and distinct products. In the present case Group III is drawn to the production of a stabilized dihydrolipoic acid while Group IV is drawn to a beneficial compound. The method steps of claim 13 and 16 are also different (i.e. claim 16 does not require the addition of ethanol).

#### UNRELATED INVENTIONS

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are the dihydrolipoic acid compound in Group I and the process to produce a

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beneficial compound in Group IV. Group I is an unrelated product that that is not necessarily formed by the process listed in Group IV.

#### UNRELATED INVENTIONS

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are the culture media of Group II and the process to produce a beneficial compound in Group IV. Group II is an unrelated product that is not necessarily formed by the process listed in Group IV.

#### UNRELATED INVENTIONS

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are the culture media of Group II and the process to prepare a dihydrolipoic acid in Group III. The culture media of Group II is not required to perform the process of Group III. The applicant is advised that the limitation on claim 13 requires the culture media listed in claim 3, not the culture media in claim 4.

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**REASON FOR RESTRICTION**

The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, and distinctness.

**ELECTION OF SPECIES**

In addition if Group II is elected, a further election of species must be made.

This application contains claims directed to the following patentably distinct species:

Groups	Claims	Species to Elect
II	5	The probiotic organisms listed in claim 5: Lactobacillus, Bifidobacterium, Enterococcus, Streptococcus thermophilus and combinations thereof
II	6	If Lactobacillus is elected from claim 5, a further election of one of the species listed in claim 6 is required
II	7	If Bifidobacterium is elected from claim 5, a further election of one of the species listed in claim 7 is required
II	8	If Enterococcus is elected from claim 5, a further election of one of the species listed in claim 8 is required

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The species are independent or distinct because they do not belong to any art recognized group nor do they share a substantial structural feature.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is no generic claim or claim X is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon***, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

## MULTIPLE INVENTORS

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## OCHIAI

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of



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35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## CONCLUSION

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

#### CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Thane Underdahl  
Art Unit 1651



SANDRA E. SAUCIER  
PRIMARY EXAMINER